DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 11, 2014

TELA Bio Incorporated
Ms. Donna Stauffer
Senior Regulatory Affairs Specialist
1 Great Valley Parkway, Suite 24
Malvern, Pennsylvania 19355

Re: K141053
Trade/Device Name: Ovine Tissue Matrix (OTM)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: November 19, 2014
Received: November 20, 2014

Dear Ms. Stauffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141053

Device Name
Ovine Tissue Matrix (OTM)

Indications for Use *(Describe)*
Ovine Tissue Matrix is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitted By: TELA Bio, Inc.
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Date Prepared: April 22, 2014

Device Information:

Trade Name:	Ovine Tissue Matrix (OTM) Reinforced Bioscaffold
Common or Usual Name:	Surgical Mesh
Classification Name:	Mesh, Surgical (21 CFR §878.3300, Product Code FTM)

Predicate Device: Endoform Reconstructive Template (K130547)

Device Description:

The OTM family is comprised of ovine derived extracellular matrix devices combined with polypropylene. The device is individually packaged and supplied sterile in various sizes and thicknesses to address the complexity of the soft tissue repair. The device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient.

The device is supplied "ready to use" in a peel pouch, and does not require rehydration or soaking prior to implant.

Intended Use:

Ovine Tissue Matrix is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or body wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

The device is supplied sterile and is intended for single use only.

Summary of Technological Characteristics:

Device	Ovine Tissue Matrix	Endoform Reconstructive Template
Manufacturer	TELA Bio, Inc.	Mesynthes, Ltd.
510(k) Number	Proposed	K130547
Indications for Use	Ovine Tissue Matrix is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or body wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.	Endoform Reconstructive Template is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include, but are not limited to, the following procedures: hernioplasty and repair of body wall defects. The device allows reinforcement or bridging of a deficit to obtain the desired surgical outcome.
Material	Ovine derived collagen and associated ECM components Collagen I Collagen III Polypropylene	Ovine derived collagen and associated ECM components Collagen I Collagen III Polyglycolic acid (PGA)
Design	Terminally sterilized	Terminally sterilized
Dimensions	Various sizes, up to 1000 cm^2	Various sizes, up to 200 cm^2
Thickness	Approx. 0.15-1.2 mm	Approx. 0.15-1.2 mm

Biocompatibility and Performance Data:

Biocompatibility, biomechanical bench, and *in vivo* performance testing have been conducted to evaluate the safety and performance characteristics of Ovine Tissue Matrices.

Biocompatibility testing was completed on the finished, sterile device in accordance with the requirements of ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, implantation, chronic toxicity, and pyrogenicity. Other safety testing included a viral inactivation study and residual chemical assessment. Results indicate that the device's biocompatibility profile is acceptable.

Biomechanical testing included uniaxial tensile strength, ball burst strength, and suture retention. Results indicate that Ovine Tissue Matrices are equivalent to the predicate device and meet the requirements for their intended use.

An *in vivo* study has demonstrated the safety and effectiveness of Ovine Tissue Matrix in a model of soft tissue reinforcement.

Conclusion:

Ovine Tissue Matrix is substantially equivalent to Mesynthes' Endoform Reconstructive Template (K130547), which has been cleared by FDA for the same intended use and indications. In addition, OTM has similar technological characteristics and principles of operation as the predicate device.

The minor technological differences between OTM and the predicate device do not raise new questions of safety and effectiveness. Performance and preclinical data demonstrate that OTM is as safe and effective as the predicate device.